

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

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HEATHER THOMAS,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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No. 18-1948V

Special Master Christian J. Moran

Filed: August 11, 2023

Reissued: August 11, 2023

Anne C. Toale, Maglio, Christopher and Toale, Sarasota, FL, for petitioner;
Tyler King, United States Dep't of Justice, Washington, D.C., for respondent.

PUBLISHED DECISION DENYING COMPENSATION¹

Seeking compensation pursuant to the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa–10 through 34 (2012), Heather Thomas claims that an influenza vaccine caused her to suffer Lambert-Eaton myasthenic syndrome. Am. Pet., filed June 1, 2021. Ms. Thomas retained an expert to support her claim and the Secretary countered with a different expert. The parties advocated for their respective positions in briefs filed before a hearing was held on July 18-19, 2023.

At the end of the hearing on July 19, 2023, Ms. Thomas was found not entitled to compensation. The primary obstacle was that Ms. Thomas failed to present a persuasive theory to explain how a flu vaccine can cause LEMS. Relatedly, Ms. Thomas did not persuasively establish that the flu vaccine did cause her LEMS. Consequently, Ms. Thomas failed to meet her burden of proof.

¹ After this decision was issued on July 21, 2023, Ms. Thomas sought redaction of one sentence. Ms. Thomas established good cause for the redaction. The decision is being reissued with this one modification.

I. Facts²

Ms. Thomas was born in 1974. Exhibit 1 at 3. She was employed by Advocate Sherman Hospital, and enjoyed various activities, sports, and outings. Exhibit 26 at ¶ 2, 5; Exhibit 25. Her medical history included hyperthyroidism, hypertension, hyperlipidemia, polycystic ovarian disease, leukopenia, eczema, and rheumatoid arthritis, and she regularly saw a doctor for problems related to hyperthyroidism. See, e.g., Exhibit 4 at 107; Exhibit 14 at 2; Exhibit 26 at ¶ 3.

The expert whom Ms. Thomas retained (Dr. Andrew Pachner) emphasized that Ms. Thomas's medical history from before the vaccination included autoimmune diseases. Dr. Pachner assumed that before the vaccination, Ms. Thomas had developed antibodies associated with LEMS. However, there is no evidence supporting (or contesting) this assertion regarding pre-vaccination LEMS antibodies.

Ms. Thomas received the flu vaccine on September 26, 2017 when she was 43 years old. On October 9, 2017, thirteen days after the vaccination, Ms. Thomas presented to Advocate Sherman Hospital with a chief complaint that her legs felt heavy and had unexplained bruises. Exhibit 5 at 2. The heaviness was described as beginning two and a half weeks prior and progressively worsening. Id. She was diagnosed with bilateral lower extremity weakness and advised to follow up with her primary care provider in a day or two. Id. at 4.

Mr. Thomas went to her primary care provider, Dr. Kushleen Dhillon, on October 10, 2017 for muscle weakness. Exhibit 3 at 5. She reported progressive weakness in her lower legs, which now extended to her upper legs. Id. at 15. Ms. Thomas stated that, since her flu shot two weeks prior, she had difficulty bending down and could not lift her legs much. Id. She had gone to Disney World from October 4-9, but had to use a stroller as a walker and tired easily. Id.; Exhibit 9 at 66. The night of October 9, she was unable to walk upstairs and had to crawl up using the banister. Exhibit 3 at 15. She noted progressive bruising on her legs and was starting to feel her arms tire as she brushed her hair. Id.

Dr. Dhillon noted that, a month prior, Ms. Thomas's lab work was in the normal range. Id. at 16. The doctor wrote: "recent flu shot has to be considered"

² The parties basically agreed that the medical records accurately describe events taking place contemporaneously when the medical record was created. The parties also basically agree that the chronology of relevant events in Ms. Thomas's life is relatively short. Accordingly, the recitation of facts is correspondingly brief.

and listed Guillain-Barre syndrome (GBS), West Nile virus, or a central nervous system issue as possible diagnoses. Id. Dr. Dhillon told Ms. Thomas to go to the emergency room “right away as this needs to be immediately evaluated and scanned.” Id.

Ms. Thomas presented to the emergency department at Advocate Sherman Hospital that same day. Exhibit 9 at 2. She stated that she had been experiencing bilateral leg weakness for 2-2.5 weeks, beginning “a few days” after she’d received her flu shot and gradually worsening. Id. at 2, 66. Ms. Thomas again reported some upper extremity weakness. Id. at 66. She was diagnosed with possible GBS/acute inflammatory demyelinating polyneuropathy (AIDP), or myasthenia gravis. Id. at 67-68, 71. She was started intravenous immunoglobulin (IVIG) treatment for five days. Id. at 71. She followed up with Dr. Dhillon on October 17, and reported that she felt significantly better, although she still had some weakness and significant fatigue when climbing stairs. Exhibit 3 at 12, 14.

An EMG was done on December 1, 2017. Exhibit 14. The conclusion stated:

This is an abnormal study. There is electrodiagnostic evidence suggestive of a mild, acute-subacute motor axonal neuropathy effecting all 4 extremities. There is no electrodiagnostic evidence of a sensory neuropathy, demyelinating neuropathy, entrapment neuropathy or radiculopathy affecting the upper or lower extremities. In light of the reported symptoms of acute weakness/[flaccidity] improved after treatment with IVIG, the possibility of acute motor axonal neuropathy (AMAN) should be considered. Clinical correlation is advised.

Id. at 5. Ms. Thomas’ diagnosis was thus updated to AMAN. Id. at 2.

Ms. Thomas visited neuromuscular specialist Dr. Daniele Anderson on January 3, 2018. Exhibit 6. The assessment found GBS, AMAN, low back pain, and bilateral leg weakness. Id. at 6. Ms. Thomas continued to receive physical therapy and monthly IVIG treatments throughout 2018. See Exhibits 12, 13, 15.

Ms. Thomas went to the Mayo Clinic on January 21, 2019 for an evaluation of GBS vs. chronic inflammatory demyelinating polyneuropathy (CIDP). Exhibit 16 at 1. An EMG was performed, and found electrodiagnostic evidence of a pre-synaptic defect of neuromuscular transmission, indicative of Lambert-Eaton myasthenic syndrome (LEMS). Id. at 23-24, 27. Ms. Thomas returned on January 23 to discuss the test results, and was informed that LEMS is “primarily due to

either an autoimmune process or paraneoplastic process (most often due to small cell lung cancer).” Id. at 118. It was later confirmed that Ms. Thomas’s LEMS is autoimmune and not paraneoplastic. See Exhibit 18 at 9; Exhibit 57 at 10.

In the years since her LEMS diagnosis, Ms. Thomas has been treated with various medications, including Mestinon, Firdapse, Ruzurgi, and Cellcept. Exhibit 20 at 8-9, Exhibit 27 at 134. She restarted immunotherapy treatments in September 2019, and was prescribed prednisone during an IVIG shortage. Exhibit 20 at 9. [redacted.] Ms. Thomas is attending physical therapy again for musculoskeletal pain due to the IVIG treatments. Exhibit 58 at 22.

The remaining medical records do not meaningfully affect whether Ms. Thomas is entitled to compensation. Therefore, although these records have been reviewed, they are not set forth in this decision.

II. Procedural History

Ms. Thomas initially alleged a flu vaccine caused her to develop GBS. Pet. at 4, filed Dec. 20, 2018. She submitted medical records on various dates. Ms. Thomas filed a status report on July 23, 2019, noting that she was diagnosed with LEMS in January 2019.

The Secretary maintained that Ms. Thomas was not entitled to compensation. Resp’t’s Rep., filed Feb. 3, 2020, at 1. The Secretary first addressed the on-Table claim for GBS, arguing that Ms. Thomas did not meet the Table criteria as it was more likely that she suffered from LEMS than GBS. Id. at 7-9. The Secretary then argued that an off-Table claim for LEMS should likewise fail, as Ms. Thomas had not yet offered a reputable medical or scientific theory showing that the flu vaccine was the cause of her LEMS, and the medical records did not support a more-likely-than-not causal relationship. Id. at 9.

To assist with the presentation of expert reports, a set of instructions was proposed in draft form on February 25, 2020. A final version of the instructions was issued on March 13, 2020, accommodating Ms. Thomas’s request to edit the time frames referenced as examples to conform with the Table time frames. See Pet’r’s Status Rep., filed Feb. 26, 2020.

Ms. Thomas filed expert reports from Dr. Andrew Pachner on April 27, 2020 (Exhibit 28), November 30, 2020 (Exhibit 49), and June 28, 2021 (Exhibit 64). Dr. Pachner graduated from medical school in 1975 and has taught at various medical schools. Currently, Dr. Pachner is a professor of neurology at Dartmouth-Hitchcock Medical Center and Geisel School of Medicine at Dartmouth, and

Director of the MS Center at Dartmouth. Exhibit 28 at 1. His career and research have been focused on clinical and basic neuroimmunology and neuroinfectious disease. Id.

The Secretary filed expert reports from Dr. Neil Romberg on August 28, 2020 (Exhibit A) and February 1, 2021 (Exhibit C). Dr. Romberg earned his medical degree in 2004. Dr. Romberg currently is an associate professor of pediatrics at the University of Pennsylvania and an attending physician at the Children's Hospital of Philadelphia, where he is Chair of Pediatric Immunology Research. Exhibit A at 1; Exhibit D. The primary focus of his post-doctoral work was B cell tolerance. Id.

After being asked whether she wished to proceed to the briefing stage, Ms. Thomas stated that she was "of the opinion that further settlement negotiations would be appropriate before expending a significant amount of time briefing the case for hearing." See Order, issued Mar. 23, 2021; Pet'r's Status Rep., filed Apr. 6, 2021. The Secretary responded on May 13, 2021, stating he had no interest in settlement and intended to continue defending the case. Accordingly, the undersigned issued an order for briefs on May 26, 2021. The briefing schedule was twice amended to give the parties additional time to prepare their cases. See Order, issued June 29, 2021; Order, issued Aug. 30, 2021.

On June 1, 2021, Ms. Thomas filed an amended petition reflecting a claim based on LEMS rather than GBS. Ms. Thomas filed her 62-page brief on September 29, 2021, and moved for a ruling on the record. The Secretary filed his 18-page brief on December 29, 2021. The Secretary relied primarily on expert reports in his brief and did not cite medical articles, and was given the opportunity to file a report as to why any articles he had filed should not be struck from the record. Order, issued Jan. 18, 2022. The Secretary responded on February 1, 2022. Ms. Thomas filed a reply on February 9, 2022.

After the undersigned determined that a hearing was appropriate, the parties selected July 18 and July 19, 2023 as dates for a virtual hearing. See Order, issued Mar. 8, 2023; Order, issued Apr. 13, 2023. On May 5, 2023, Ms. Thomas filed a motion to amend the schedule, expressing an interest in retaining an immunologist and filing additional expert reports. Respondent opposed the motion on May 16, and petitioner replied on May 23. A recorded status conference was held on May 24 to discuss the motion. The undersigned did not decide on the motion during the conference, and stated that he would issue an order within the next week. The same day, before any decision had been made, Ms. Thomas withdrew her motion. See Order, issued May 24, 2023.

Three weeks prior to the hearing, the undersigned issued an order with two tentative findings. First, the undersigned tentatively found that Ms. Thomas could not proceed on a theory of molecular mimicry, which Dr. Pachner briefly mentioned in his first report, as the evidence did not meet Ms. Thomas's burden and the argument about the evidence was not sufficiently robust. Second, the undersigned tentatively found that, contingent upon a persuasive showing regarding the medical theory, Ms. Thomas met Althen prong 3. See Order, issued June 26, 2023. Ms. Thomas filed a response on June 30, noting that she had voluntarily withdrawn a theory of molecular mimicry and agreeing with the tentative finding on onset.

The hearing was held on July 18-19, 2023. Dr. Pachner, Dr. Romberg, and Ms. Thomas testified. As mentioned earlier, Ms. Thomas was found not entitled to compensation at the conclusion of the hearing and the present document memorializes the reasons for that outcome.³

III. Standards for Adjudication

A petitioner is required to establish her case by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). The preponderance of the evidence standard requires a “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the [judge] of the fact’s existence.” Moberly v. Sec’y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec’y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). The standard of proof does not vary depending upon the quality and quantity of scientific evidence available. Caves v. Sec’y of Health & Hum. Servs., 100 Fed. Cl. 119, 143 (2011), aff’d without opinion, 463 F. App’x 932 (Fed. Cir. 2012).

Distinguishing between “preponderant evidence” and “medical certainty” is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec’y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master’s decision that petitioners were not entitled to compensation); see also Lampe v. Sec’y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec’y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed.

³ The present decision is being issued on an expedited basis to facilitate Ms. Thomas’s submission of a motion for review if Ms. Thomas wishes. The decision is being issued before a transcript has been created.

Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

Petitioners bear a burden "to show by preponderant evidence that the vaccination brought about [the vaccinee's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

IV. Analysis

As a preliminary matter, the background of the two experts may be compared. Copenhaver v. Sec'y of Health & Hum. Servs., 129 Fed. Cl. 176, 183 (2016) (citing supporting cases); Depena v. Sec'y of Health & Hum. Servs., No. 13-675V, 2017 WL 1075101 (Fed. Cl. Spec. Mstr. Feb. 22, 2017), mot. for rev. denied, 133 Fed. Cl. 535, 547-48 (2017), aff'd without op., 730 F. App'x. 938 (Fed. Cir. 2018). Although Dr. Pachner and Dr. Romberg are both qualified to testify about immunologic issues, the background and experience of Dr. Romberg strengthen his opinions regarding immunology vis-à-vis the competing opinions from Dr. Pachner. Dr. Pachner has published research on B cell subset accumulation and antibody production in the central nervous system, as seen in multiple sclerosis, using mice infected with the Theiler's murine encephalomyocarditis virus as a model. See, e.g., Exhibits 50, 52, 53. However, Dr. Romberg is board certified in immunology and Dr. Pachner is not. Dr. Romberg participated in a fellowship in immunology and Dr. Pachner did not. Dr. Romberg teaches courses in immunology, including on B cells. Dr. Pachner's current teaching is not as focused on immunologic topics. Because much of the dispute between Dr. Pachner and Dr. Romberg concerns the function of B cells, Dr. Romberg's expertise in immunology strengthens his opinion.⁴

Dr. Pachner certainly has more experience in neurology. He has treated more than one hundred patients with a different disease of the neuromuscular junction, myasthenia gravis. But, on the specific disease afflicting Ms. Thomas, LEMS, Dr. Pachner treated one patient before 2000 and has not had any patients since that time. Dr. Pachner has also consulted on as many as five LEMS patients. If the experts disputed whether Ms. Thomas suffered from LEMS, then Dr.

⁴ During Dr. Pachner's testimony, he recognized that in his reports, he used immunologic terms imprecisely. A similar flaw was not identified in Dr. Romberg's reports.

Pacher's superior credentials in neurology would quite likely be decisive. But, Dr. Pachner and Dr. Romberg dispute how the flu vaccine would affect components of the immune system, a topic more in the purview of Dr. Romberg.

The opinions of Dr. Pachner and Dr. Romberg are the foundations for the analysis that follows. This evaluation focuses on the prongs of Althen.

A. Althen prong 1

Pursuant to Althen, a petitioner must present "a medical theory causally connecting the vaccination and the injury." Althen, 418 F.3d at 1278.

Here, Ms. Thomas proceeded "solely on the defective B-cell signal theory." Pet'r's Status Rep., filed June 30, 2023, at 2. Arguably, during the hearing Dr. Pachner added a theory based upon bystander activation. These theories are discussed below after a brief presentation of underlying immunology.

1. Immunology

Two aspects of immunology are relevant. The first is the development of B cells. The second concerns the etiology of LEMS.

First, when the body encounters a foreign substance, the adaptive immune system can be engaged. One part of the adaptive immune system is the B cells.

B cells and their resulting antibodies are created through a process, which Dr. Pachner described as miraculous. B cells develop through several stages, beginning in the bone marrow. Dr. Pachner referred to the following diagram to demonstrate the developmental stages:

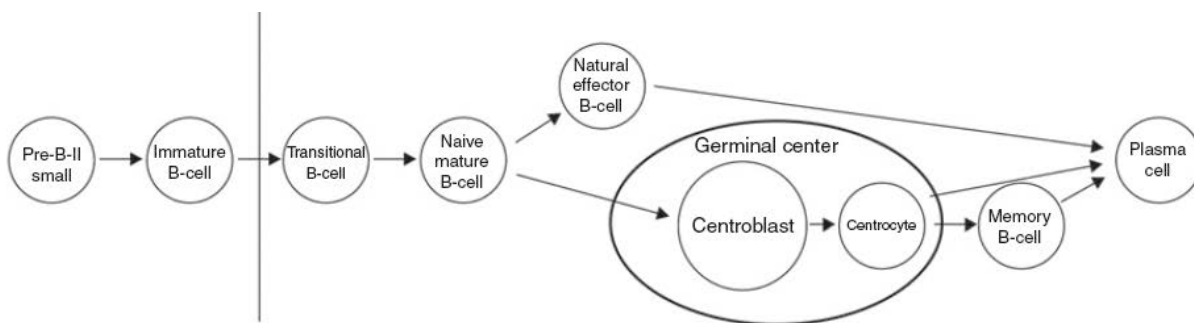


Exhibit 83 at 2. One end of this process is the creation of a plasma cell. (Another end, which is not depicted on this chart, is the removal of B cells that might break tolerance and attack the body's own tissues.) Plasma cells manufacture vast amounts of antibodies that respond to invading organisms.

Antibodies, in rare cases, also can attack the body's own tissues, causing an autoimmune disease. LEMS is an example of an autoimmune disease. In LEMS, an antibody attacks portions of the neuromuscular junction named voltage gated calcium channels, typically abbreviated "VGCCs." The antibodies' interaction with the acetylcholine receptor of the neuromuscular junction impairs the passage of calcium and this reduction, in turn, interferes with a person's muscles.

Although doctors are aware that antibodies cause LEMS, why the autoantibodies are able to affect a person's acetylcholine receptor in extremely rare cases not known. Dr. Pachner, as mentioned, presented a theory involving defective B cell signaling.

2. Defective B Cell Signaling

Dr. Pachner's written reports and oral testimony regarding the role of the flu vaccine were, unfortunately, not a model of clarity. Cross-examination clarified that his opinion contained several parts. As a foundation, Dr. Pachner asserted that before the vaccination, Ms. Thomas had defective B cell tolerance, meaning she was less capable of downregulating any immunoreactivity. Dr. Pachner indicated that Ms. Thomas's defective B cell tolerance is demonstrated by the other autoimmune diseases she suffered. Dr. Pachner further assumed that before the vaccination, Ms. Thomas had a store of memory B cells, which were specific for VGCCs. Ms. Thomas did not suffer from LEMS before the vaccination because the antibodies were not of sufficient quantity or quality to cause disease. In Dr. Pachner's view, the flu vaccination, however, upset this status by stimulating the dormant memory B stems to move along a pathway to become plasma cells that generated the antibodies against the VGCCs.

Ms. Thomas and Dr. Pachner marshalled very little evidence about the flu vaccine. In the hearing, Ms. Thomas drew attention to a portion of Dr. Pachner's first report in which Dr. Pachner wrote: "the influenza vaccination on September 27, 2017 was an immunostimulatory event triggering an activation and replication of autoimmune B cells producing anti-VGCC antibodies." Exhibit 28 at 12. However, in this passage, Dr. Pachner does not cite any literature explaining why the flu vaccine would engage B cells for the voltage gated calcium channels. Similarly, Ms. Thomas devoted perhaps three pages of a sixty-page brief to the topic of the flu vaccine. See Pet'r's at 51-54.

In the hearing, Ms. Thomas's direct examination solicited little testimony from Dr. Pachner about the flu vaccination. Throughout all his testimony, not just on direct examination, Dr. Pachner relied upon a passage from a 2021 article:

“Thus, alternative routes to plasma cell generation may exist, including the use of cytokine or TLR [toll-like receptor] signals generated by unrelated ongoing immune response to trigger [memory B cell] differentiation into plasma cells.” Exhibit 69 (Michael P. Cancro and Mary M. Tomayko, “Memory B cells and plasma cells: The differentiative continuum of humoral immunity”) at 8.⁵

This passage is too slender a reed to uphold Ms. Thomas’s burden to present a reliable medical theory. Various points limit its persuasive value. First, as Dr. Romberg pointed out, the authors write “alternative routes . . . may exist.” The use of the term “may” suggests a degree of speculation, and the authors propose further investigation. Second, even if some “unrelated ongoing immune response” could contribute to the generation of plasma cells, Ms. Thomas has not presented any persuasive evidence that the response to the flu vaccine could be one such instigating factor.

Another problem is that Dr. Pachner has not persuasively accounted for the role of memory B cells. Under his theory, Ms. Thomas was burdened with memory B cells specific for the VGCCs before the vaccination. Because the immune system can readily access the neuromuscular junction, the circulating memory B cells would routinely come in contact with their target antigen, the VGCCs. As Dr. Romberg explained, this interaction should stimulate the production of antibodies. The flu vaccine would not be required.

Although literature is not required, Althen, 418 F.3d at 1280, “a scientific theory that lacks any empirical support will have limited persuasive force.” Caves, 100 Fed. Cl. at 134. Here, the article that most closely discusses the flu vaccine and LEMS together is a case report. Exhibit 45 (H. Ansakorpi et al., “Lambert-Eaton myasthenic syndrome following H1N1-influenza vaccination – a case report,” 126 Acta Neurol Scand e25 (2012)). As Dr. Romberg indicated, a case report is the least rigorous form of medical evidence. Dr. Pachner, too, indicated that the case report was not too important to his opinion. Giving little weight to isolated case reports is in accord with many cases. See K.O. v. Sec’y of Health & Hum. Servs., No. 13-472V, 2016 WL 7634491, at *11-12 (Fed. Cl. Spec. Mstr. July 7, 2016) (discussing appellate precedent on case reports).

⁵ Ms. Thomas filed the manuscript version of the article. 00 IMMUNOL. REV. 1 (2021). The published article is 303 IMMUNOL. REV. 72 (2021).

For these reasons, Ms. Thomas has not met her burden regarding B cell signaling defect. It may be the case that people suffering from LEMS, such as Ms. Thomas, have something wrong with how they produce B cells. However, Ms. Thomas has not persuasively connected any deficiency in B cells to the flu vaccine.

3. Bystander Activation

Near the end of the hearing, there was testimony about bystander activation. Whether bystander activation is a theory separate from the defective B cell signaling theory or whether bystander activation is the same theory with a different name is not entirely clear. If bystander activation is the same as the defective B cell signaling theory, then it fails for the reasons stated above.

But even if the bystander activation theory were an independent theory, it is unpersuasive due to lack of development. Dr. Pachner did not use the term “bystander activation” in any of his reports before the hearing. See Exhibits 28 (filed Apr. 27, 2020), 49 (filed Nov. 30, 2020), 64 (filed June 28, 2021). He also did not use the term “bystander activation” in his supplemental statement regarding literature. See Exhibit 72 (filed June 12, 2023). Apart from citations, the term “bystander” appears in only two of the articles filed by Ms. Thomas: once in Exhibit 36, and once in Exhibit 40. In Ms. Thomas’s brief, the term “bystander activation” appears twice but she did not assert that she was bringing forward this theory. See Pet’r’s Br. at 45 and 52. Furthermore, before the hearing, Ms. Thomas stated that she “has chosen to proceed to hearing solely on the defective B-cell signaling theory.” Pet’r’s Status Rep., filed June 30, 2023. When Dr. Pachner testified on the first day of the hearing, he did not use the term “bystander activation.”

Thus, to the extent that bystander activation represents a theory distinct from the defective B cell signaling theory, the bystander activation theory is an afterthought. To be sure, the bystander activation theory is not being rejected simply because it was presented late. The bystander theory was not supported with any persuasive evidence showing how the flu vaccination could be part of the bystander activation theory to cause LEMS.

When petitioners present bystander activation in a conclusory manner, special masters may decline to endorse that theory. See Temes v. Sec’y of Health & Hum. Servs., 151 Fed. Cl. 448, 461-62 (2020), Shapiro v. Sec’y of Health & Hum. Servs., 105 Fed. Cl. 353, 359 (2012), aff’d without op., 503 F. App’x 952

(Fed. Cir. 2013). So, too, in Ms. Thomas's case, the bystander activation was not persuasively supported.

Accordingly, for these reasons, Ms. Thomas has not met her burden regarding Althen prong 1. Because a lack of proof on one prong means that a petitioner cannot receive compensation, Hibbard v. Sec'y of Health & Hum. Servs., 698 F.3d 1355, 1365 (Fed. Cir. 2012); Holmes v. Sec'y of Health & Hum. Servs., 115 Fed. Cl. 469, 488 (2014); Vaughan v. Sec'y of Health & Hum. Servs., 107 Fed. Cl. 212, 222 (2012); the other prongs are extraneous. Nonetheless, these topics are briefly discussed.

B. Althen prong 3

The timing prong actually contains two parts. A petitioner must show the "timeframe for which it is medically acceptable to infer causation" and the "onset of" the disease occurred in this period. Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 542-43 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff'd without op., 503 F. App'x 952 (Fed. Cir. 2013). The anticipated interval largely derives from the offered theory. Langland v. Sec'y of Health & Hum. Servs., 109 Fed. Cl. 421, 443 (2013).

Here, Dr. Pachner asserted that Ms. Thomas's LEMS was manifest within an appropriate time after the vaccination. Exhibit 28 at 11. Dr. Romberg did not contest this assertion. The lack of contrary evidence contributed to a Tentative Finding, issued June 26, 2023, that Ms. Thomas had met her burden regarding Althen prong 3. During the hearing, no testimony controverted the appropriateness of the timing.

However, a finding that Ms. Thomas developed LEMS within an appropriate time after the vaccination does not mean she is entitled to compensation. Grant v. Sec'y of Health & Hum. Servs., 956 F.2d 1144 (Fed. Cir. 1992) ("Temporal association is not sufficient, however, to establish causation in fact."). Ms. Thomas is still required to establish the other Althen prongs.

C. Althen prong 2

Pursuant to Althen, a petitioner must establish "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Althen, 418 F.3d at 1278. With respect to this prong, the Federal Circuit has instructed special masters to consider carefully the views of a treating doctor. Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006).

Here, Ms. Thomas has identified one statement from a treating doctor as supporting her claim. See Pet'r's Br. at 56; see also Order for Briefs, issued May 26, 2021 at 7 (requesting this information). The statement is a January 19, 2020 letter from a doctor who treated Ms. Thomas at Mayo Clinic in January 2019, Nathan Staff, to Ms. Thomas's attorney. Exhibit 24. Dr. Staff summarized Ms. Thomas's medical history and concluded his one-letter paragraph with these sentences:

Given the rarity of Lambert-Eaton myasthenic syndrome, it is impossible to confidently associate the influenza vaccine with the development of her disease; however, Lambert-Eaton myasthenic syndrome is an autoimmune neuromuscular disease and given the flu vaccine association with other autoimmune neuromuscular diseases, it is a reasonable hypothesis that that was the trigger in her case.

Id.

Dr. Staff has not persuasively expressed an opinion that he concluded that the flu vaccine did cause Ms. Thomas's LEMS. He describes the assertion as a "reasonable hypothesis." This wording is not the same as a persuasive statement of causation. See Paterek v. Sec'y of Health & Hum. Servs., 527 F. App'x 875, 883 (Fed. Cir. 2013) (testimony that causation was "not impossible" does not support causation); Fesanco v. Sec'y of Health & Hum. Servs., 99 Fed. Cl. 28, 34 (2011) (a statement by treating physician that he was "suspicious" of vaccine-causation is not affirmative statement of causation); Doe v. Sec'y of Health & Hum. Servs., 19 Cl. Ct. 439, 450 (1990) (a statement of "highly possible" is not preponderant evidence).

Accordingly, Ms. Thomas has not met her burden regarding Althen's second prong. Because Ms. Thomas has not shown with persuasive evidence that the flu vaccine was the cause-in-fact of her LEMS, it is reasonable to conclude that the flu vaccine simply coincided with the initial manifestations of LEMS. See Exhibit A at 7.

V. Conclusion

Ms. Thomas's case is sympathetic in that she has suffered from a disease that has interfered with her life for many years. Nevertheless, special masters are

called upon to analyze the evidence dispassionately. In this case, the evidence does not show that Ms. Thomas is entitled to compensation.

The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline, can be found on the web site for the United States Court of Federal Claims.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master